

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

*The County of Cuyahoga v. Purdue
Pharma L.P., et al.,*
Case No. 17-op-45004

and

*The County of Summit, Ohio, et al. v.
Purdue Pharma L.P., et al.,*
Case No. 18-op-45090.

MDL No. 2804

Case No. 1:17-md-2804

Hon. Dan Aaron Polster

**REPLY IN SUPPORT OF NON-RICO SMALL DISTRIBUTORS’
MOTION FOR SUMMARY JUDGMENT BASED ON THEIR *DE MINIMIS* STATUS**

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PRELIMINARY STATEMENT

The Small Distributors do not, as Plaintiffs write, contend that Plaintiffs’ “injuries . . . are trifling.”¹ Instead, the Small Distributors point out that the claimed injuries are so vast—each Plaintiff describes “a slow-moving mass fatality”²—that the causes of those injuries must be similarly vast. No jury, “us[ing] . . . common sense”³ to weigh the Small Distributors’ [REDACTED] market shares and [REDACTED] collective share of allegedly suspicious orders, could find that any Small Distributor caused “the worst man-made epidemic in modern medical history.”⁴ The Small Distributors’ roles, not Plaintiffs’ alleged injuries, are trifling here.

That is why Plaintiffs have themselves trifled with the Small Distributors, *de minimis* Defendants all, throughout the litigation. In the pleadings stage, Plaintiffs tacitly concede, they did not even name as Defendants more than a dozen other distributors with similar—sometimes higher—market shares. And while in footnote 100 of Plaintiffs’ opposition they now explain away their discovery-stage motion to extend the deadline for amending complaints, Plaintiffs themselves chose the very term “*de minimis*” to describe distributors with five-percent-or-less market share for six of the nine years covered by the ARCOS data. Next, in the expert stage, Plaintiffs’ data analyst testified that [REDACTED] of distribution would qualify as a *de minimis* amount. And entering the trial stage, Plaintiffs moved to sever three of the four Small Distributor families. The sole Small Distributor left in the Track One trial, Henry Schein, has [REDACTED] percent market share, which the data analyst described unequivocally as “*de minim[i]s*.” In both word and deed, Plaintiffs have themselves treated the Small Distributors as trifling.

¹ ECF Nos. 2200/2201 at 22.

² ECF Nos. 1466/1631 at ¶ 720.

³ United States District Court for the Northern District of Ohio (Hon. Dan A. Polster), *Jury Instructions – Civil Case*, ohnd.uscourts.gov, <https://www.ohnd.uscourts.gov/sites/ohnd/files/DAP-BoilerplateCivilJuryCharge.PDF> (last visited Aug. 12, 2019).

⁴ ECF Nos. 1466/1631 ¶ 2.

ARGUMENT

I. The Small Distributors' Conduct is Measured not in a Vacuum, but an Epidemic.

In an about-face, Plaintiffs now assert that the Small Distributors' "conduct was hardly *de minimis*."⁵ Rattling off the [REDACTED]-digit figures representing the Small Distributors' total MMEs shipped (which appear far greater than dosage units), and [REDACTED] of dosage units they allege should have been flagged, Plaintiffs call these numbers "large," even "massive."⁶

But text without context is pretext. Recitations of these numbers have little meaning apart from the shipments and flagged orders of other actors. Indeed, "[s]ome other event which is a contributing factor in producing the harm may have such a predominant effect in bringing it about as to make the effect of the actor's negligence insignificant and . . . to prevent it from being a substantial factor.'" *Wilson v. AC&S, Inc.*, 864 N.E.2d 682, 698 (Ohio Ct. App. 2006) (quoting Restatement (Second) of Torts § 433 cmt. c (1965)). That is precisely the case with the [REDACTED] percent or more of shipments and more than [REDACTED] percent or more of flagged orders, by any of Plaintiffs' measures, which occurred without any one Small Distributor doing anything. In this epidemic, those numbers *render* the Small Distributors' numbers *de minimis*.

Plaintiffs concede, elsewhere, that they must prove that each Small Distributor "was a substantial contributing factor in causing the opioid *epidemic*."⁷ In their opposition, they try to do so based on two sources of evidence: (i) aggregate proof and (ii) an inference that each Small Distributor's alleged failures were "the cause of the plaintiff's harm where the injury to plaintiff was the type of injury that [the] defendant's conduct would be expected to cause."⁸ Both sources fail to generate any genuine dispute that any Small Distributor was a substantial factor here.

⁵ ECF Nos. 2200/2201 at 2.

⁶ *See, e.g., id.* at 3.

⁷ ECF Nos. 2203/2204 at 1 (emphasis added).

⁸ ECF Nos. 2200/2201 at 17.

A. Each Small Distributor's Conduct must be Considered Individually.

Because each Small Distributor's share of the market, and of flagged orders, is trivial, Plaintiffs argue first and foremost that the Small Distributors' "*aggregate*" conduct is not *de minimis*.⁹ "Each defendant's liability," however, "must be assessed individually, based on his or her own actions." *Dorsey v. Barber*, 517 F.3d 389, 399 n.4 (6th Cir. 2008).

Plaintiffs, then, cannot survive summary judgment by grouping Small Distributors' conduct together. Elsewhere, Plaintiffs have admitted as much, conceding they are "required to prove their claims against each defendant based on each defendant's wrongdoing."¹⁰

B. The "Opioid Epidemic" is not the Type of Injury that Distributors with █-Percent-or-Less Market Share Would be Expected to Cause.

Plaintiffs rely heavily on the idea that "[o]nce a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct, he has done enough to withstand summary judgment on the ground of absence of causation."¹¹ But no one would expect that the Small Distributors' *de minimis* shipments of opioid products would result, or even could result, in an epidemic.

No Small Distributor shipped more than █ percent of the total dosage units in Cuyahoga or Summit Counties. And as detailed below, each shipped less than █ percent (or none) of the orders Plaintiffs contend should have been flagged. However effective their controls against diversion, each Small Distributor lacked the agency in these markets to cause, or contribute substantially to cause, a "tsunami"-like epidemic of "absolute total devastation."¹²

⁹ ECF Nos. 2200/2201 at 1–4 (emphasis added).

¹⁰ ECF Nos. 2203/2204 at 2.

¹¹ ECF Nos. 2200/2201 at 17 (incorporating ECF Nos. 2203/2204 at 35).

¹² ECF No. 2203/2204 at 6.

The Small Distributors accepted, for purposes of argument in their moving papers, the flagged orders Plaintiffs attributed to them. So any failing in the Small Distributors' SOMS is accounted for in Plaintiffs' flagged orders and immaterial to this motion.

Still, Plaintiffs insist on litigating this distraction and on characterizing the Small Distributors' respective shares of the market and of flagged orders as more than *de minimis*. Here, the Small Distributors briefly respond, individually, to these "individuated" arguments.

Henry Schein. Despite Plaintiffs' efforts to draw attention to the company's size over its share of opioid sales, Plaintiffs do not dispute what the pertinent ARCOS data¹³ reflects—between 2006 and 2014, Schein shipped a total of [REDACTED] orders of opioids to Summit County; none of these orders exceeded [REDACTED] dosage units; and the resulting sales totaled merely \$24,405 over 13 years—yet seek *billions* of dollars from Schein.¹⁴ And there should be little surprise that Schein neither shipped nor reported any suspicious orders involving Summit County to the DEA given the miniscule volume of orders at issue, which Plaintiffs' own experts acknowledge is *de minimis*.¹⁵ Indeed, Plaintiffs fail to justify including in this lawsuit a distributor that sold just [REDACTED] percent (in MMEs) of the opioids in Summit. Instead, Plaintiffs distract with false and irrelevant representations regarding two of Schein's former customers, Drs. Adolph Harper and Brian Heim. Although such misrepresentations are wholly irrelevant and insufficient to defeat summary judgment regarding Schein's *de minimis* status, Schein nonetheless corrects the record below.

¹³ For purposes of this discussion, Schein references Plaintiffs' own expert data and output files.

¹⁴ See Ex. 1, Schein transaction data taken from McCann ARCOS output files; Ex. 2, Harper and Heim totals taken from HSI Opioid Sales 1.1.06 to 12.31.18.xlsx and 2019.05.19 – HSI Total Transactions to Summit County 2006-2018.xlsx; Ex. 3, Supp. Rep. of Robert Maness, June 6, 2019, Table 2.

¹⁵ ECF No. 1966-17 at 555:11–17 (agreeing Schein's [REDACTED] % market share is *de minimis*); ECF No. 1969-18/19 at 393:20–394:6 (Rafalski confirming he knows of no suspicious orders shipped or diversion caused by Schein in Summit).

Regarding Dr. Harper, Plaintiffs allege he was Schein's "largest customer in Summit."¹⁶ That is not true—not by a long shot. Schein's previously produced sales data from 2006 to 2018 reflects that Dr. Harper's purchases represent only 0.03 percent of Schein's total sales to Summit County in the same period.¹⁷ More importantly, Plaintiffs' argument that Dr. Harper's "diversion of opioids provided to him by HS resulted in at least eight deaths, and he was sentenced to ten years in prison" is also false.¹⁸ Schein's last sale of opioids to Dr. Harper was on April 7, 2009, and he did not begin operating a "pain management facility" until September 2009.¹⁹ His misconduct occurred more than five months after Schein's final shipment. Further, as Plaintiffs admit, Schein does not sell to pharmacies, and so could not have supplied the opioids used to fill prescriptions written by Dr. Harper.

Plaintiffs likewise misstate the evidence with respect to Dr. Heim. He was *not* Schein's second-largest customer in Summit.²⁰ In fact, Dr. Heim's total purchases of all products was just 0.02 percent (\$14,484) of Schein's total sales in Summit.²¹ While Plaintiffs blame Schein for shipping to him at all given his prior conviction, the evidence shows (1) that conviction was over a decade old before he became a customer, (2) the State of Ohio deemed it appropriate after a lengthy period of probation and treatment to reinstate his medical license without restriction, and (3) Schein conducted the necessary state and federal license checks to confirm his eligibility to order and receive opioids.²² And like Dr. Harper, Dr. Heim's 2015 conviction was for improper *prescription practice* pertaining to opioids that were not supplied by Schein.²³ Further, the DEA

¹⁶ ECF Nos. 2200/2201 at 10.

¹⁷ Ex. 3, Table 2; *see also* Ex. 2.

¹⁸ ECF Nos. 2200/2201 at 10.

¹⁹ *See* Ex. 2; Ex. 4, Gov't's Sentencing Mem., at 2, Jan. 23, 2015, ECF No. 74, 5:14-cr-00096-JRA (N.D. Ohio).

²⁰ ECF Nos. 2200/2201 at 10.

²¹ Ex. 2.

²² *See* Ex. 5, Heim – Ohio Medical Board License Lookup; Ex. 2; Ex. 6, HSI-MDL-0001198–HSI-MDL-0001210.

²³ Ex. 7, Information, ¶ 14, Nov. 14, 2014, ECF No. 1, 5:14-cr-00412-DAP (N.D. Ohio).

was well aware that Schein distributed some opioids to Dr. Heim, but neither the DEA nor DOJ ever took any related action against Schein.

For Dr. Heim, Dr. Harper, or any other practitioner in Summit County, neither Plaintiffs' experts nor the evidence identifies a single suspicious order shipped by Schein.²⁴ Dr. McCann, however, agrees unequivocally that Schein is *de minimis*. The undisputed evidence shows that Schein could not have been a substantial factor in causing the opioid epidemic.

Anda. According to Plaintiffs' data analyst, Dr. McCann, Anda's overall market share for opioids in both Cuyahoga and Summit from 2006 to 2014 was [REDACTED] percent. Thus:

Cuyahoga County: Anda Market Share ²⁵	MME	Dosage Units	Transactions (Orders) ²⁶
	[REDACTED]	[REDACTED]	[REDACTED] ²⁷

Summit County: Anda Market Share ²⁸	MME	Dosage Units	Transactions (Orders)
	[REDACTED] %	[REDACTED] %	[REDACTED] %

Moreover, using the exact same data supplied by McCann, Anda cannot be held liable as a "substantial contributor" for shipping orders Plaintiffs say required flagging.²⁹ Anda's share of

²⁴ Plaintiffs falsely assert that "Dr McCann was not able to calculate the amount of orders HS should have flagged" because "HS supplied insufficient information in discovery." ECF Nos. 2200/2201 at 8. Dr. McCann performed his transaction analysis using ARCOS Data from 2006 to 2014, only supplementing the ARCOS data with data produced by the Defendants where such transactions were not available in the ARCOS data. ECF No. 1999 at ¶ 130. It is simply false that Dr. McCann could not perform his analysis of flagged orders for Schein. Dr. McCann admits he has no opinion whatsoever regarding Schein because Schein has no sales to chain or retail pharmacies in either Summit or Cuyahoga Counties. ECF No. 1966 at 552:12–22.

²⁵ See ECF Nos. 2200/2201, Ex. 1 at 3779, 3783 (App. 9 of McCann Rep.).

²⁶ The total number of distributor transactions in Cuyahoga from 2006–2014, as determined by McCann, was [REDACTED]; and for Summit during that same period the number is [REDACTED]. See ECF Nos. 2000–14/2001–14 at Tables 17 and 21.

²⁷ As determined by Dr. McCann, Anda's total transactions for the period 2006–2014 were Cuyahoga County: 2903 transactions and Summit County: 3339 transactions. See Ex. 8, Anda, Inc. Data Taken from Supp. 3 – Data Files.

²⁸ See ECF Nos. 2200/2201, Ex. 1 at 3849, 3852 (App. 9 of McCann Rep.).

²⁹ In the Opposition, Plaintiffs rely upon one of several methods used by its experts to identify "suspicious orders": the so-called "Maximum Daily Dosage Units Threshold Flagged Transactions" methodology. Plaintiffs ignore the

these orders in Summit for the period 1996–2018 is [REDACTED] *percent*.³⁰ Even accepting Plaintiffs’ flawed “methodologies,” Anda’s shipment of less than one-half of one percent of the orders allegedly shipped improperly into each county over the course of more than twenty years cannot support a finding that Anda’s conduct had “a substantial as distinguished from a merely negligible effect in bringing about plaintiff’s harm.”³¹

Because the data is dispositive, Plaintiffs’ arguments concerning the adequacy of Anda’s SOMS are irrelevant, lack a critical foundation, and thus should be disregarded. Whether Anda’s conduct complied with any applicable standard of care is a question requiring expert testimony. Neither of Plaintiffs’ purported SOMS experts offered any opinion as to Anda’s SOMS. In fact, not only are both of their reports entirely silent as to Anda, James Rafalski expressly confirmed at his deposition that he has not done any such analysis or reached any conclusions about Anda’s conduct.³² Having failed to disclose an expert who has considered Anda’s SOMS, and accordingly having offered no expert opinion that the program is or was deficient in any way, there is now no issue that can be considered by a jury or the Court.

Plaintiffs’ conclusory assertions about a handful of documents from Anda’s files³³—none of which relate in any way to the question of whether, as a matter of law, Anda’s share of the

fact that James Rafalski did not choose this methodology based on any evaluation of its efficacy or its value as a mechanism for identifying suspicious orders, but because it was allegedly used by another Defendant at some point in the timeframe of his report. *See* ECF No. 1969-18 at 164:4–12.

³⁰*See* ECF Nos. 2000-14/2001-14 at Table 33. Not surprisingly, Plaintiffs ignore the one methodology which, though also flawed, was endorsed by Rafalski—the “Trailing Six-Month Maximum Threshold.” *See* ECF No. 1969-18 at 480:17–481:20. Anda’s share of “should have been flagged” transactions in Summit using this method for the period 1996–2018 is [REDACTED]. *See* ECF Nos. 2000-14/2001-14 at Table 25. In Cuyahoga, Anda’s share would be [REDACTED] for the “Maximum Daily Dosage Units Threshold Flagged Transactions” and [REDACTED] for the “Trailing Six-Month Maximum Threshold.” *See id.* at Tables 32 and 24.

³¹ ECF Nos. 2203/2204 at 34.

³² *See* ECF No. 1969-18 at 840:5–841:23.

³³ Plaintiffs rely on sixteen documents and incomplete citations to Anda witness depositions as “evidence of [Anda’s] failed SOMs program.” ECF No. 2200/2201 at 6. Remarkably, most of the documents and testimony refer to customers located outside of Track One—and thus have no ties to the alleged shipments Anda made into Track One. *See id.* at Exs. 6, 7, 17, 18, 19, 23. Moreover, Plaintiffs’ interpretation of these documents ignores the volumes of evidence to the contrary that an expert might have considered in analyzing Anda’s SOMS.

allegedly improper conduct was a substantial factor in bringing about any claimed harm to the Plaintiffs—are thus immaterial to this motion. The Court need not consider Plaintiffs’ conjecture because none of it changes the simple and undisputed conclusion that Anda is at most a *de minimis* or negligible contributor to Plaintiffs’ alleged harm who cannot be held liable here on any of Plaintiffs’ claims.

H. D. Smith. Plaintiffs offer various attacks on H. D. Smith, but do not dispute the following facts set forth in the Small Distributors’ opening brief at pages five and eight:

Cuyahoga County: H. D. Smith’s *De Minimis* Market Share and Flagged Orders

MME	Dosage Units	Alleged Flagged Orders (depending on method used)
██████	██████	████████████████████

Put another way, Plaintiffs’ own flawed methodologies resulted in identifying at most ██████ “flagged” transactions over a 23-year period for H. D. Smith.³⁴ Plaintiffs offer no evidence refuting the fact that the H. D. Smith orders they attempt to challenge constitute only a *de minimis* percentage of the market share and “flagged” orders allegedly at issue.

Unable to offer any evidence refuting the *de minimis* nature of H. D. Smith’s alleged “flagged” orders, Plaintiffs distract from these **material** undisputed facts by arguing random claims about H. D. Smith’s SOMS and due-diligence efforts unrelated to Cuyahoga County. Plaintiffs offer no evidence or expert opinions, however, to support any claim that this miniscule number (██████ percent) of “flagged” transactions was (1) actually suspicious or (2) ever diverted. Rather than offering material evidence, Plaintiffs simply make the stunning assertion that “it is ***not unreasonable to assume*** that H.D. Smith’s opioids ***might end up being diverted*** in Cuyahoga County, and in fact, they were.”³⁵ This statement of pure conjecture is itself evidence

³⁴ ECF No. 2000-14/2001-14 at 59, 63, 67, 71, 75.

³⁵ ECF No. 2200/2201 at 13 (emphasis added).

confirming that Plaintiffs' claims against H. D. Smith constitute nothing more than unsupported speculation. None of Plaintiffs' other arguments suggest otherwise.

Plaintiffs first contend that H. D. Smith made shipments into Cuyahoga County that "should have been investigated as suspicious."³⁶ Plaintiffs rely upon McCann's opinions for this point and attempt to equate his "flagged" transactions to being "suspicious." McCann, however, offered no such opinions. To the contrary, he testified that he is offering no opinions that any of Defendants' orders were suspicious, illegal, or should have been subjected to further due diligence.³⁷ Plaintiffs have failed to present a single expert in this case attempting to offer an opinion that any of H. D. Smith's sales into Cuyahoga County were suspicious or improper in any way. Plaintiffs' representations to the contrary are completely unsupported by the record.

Plaintiffs also attempt to set up the straw man of attacking aspects of H. D. Smith's SOMs program, speculating that as a result of that program, some of H. D. Smith's sales "might end up being diverted."³⁸ Plaintiffs again attempt to do so, however, without an expert witness willing to challenge any aspect of H. D. Smith's SOMs program. Rather, Plaintiffs rely in their response on only a few immaterial documents that have no specific connection to any sales in Cuyahoga County. By way of example, Plaintiffs' response relies on an H. D. Smith document relating to issues with sales to customers in *Florida* to somehow support Plaintiffs' contention that H. D. Smith's SOMs program resulted in diversion in Cuyahoga County, Ohio.³⁹

Plaintiffs' only attempt to tie any actions by H. D. Smith to Cuyahoga County is their argument regarding Church Square Pharmacy. Plaintiffs yet again make unsupported assertions,

³⁶ ECF No. 2200/2201 at 11.

³⁷ ECF No. 1966-17 at 147-148.

³⁸ ECF No. 2200/2201 at 13.

³⁹ ECF No. 2303-5 (Ex. 46).

such as that H.D. Smith’s sales to Church Square “were shipped without investigation.”⁴⁰ First, Plaintiffs’ arguments are again unsupported by record evidence. Second, they are an immaterial red herring. The dispositive fact in this motion is that Plaintiffs’ own methodologies resulted in “flagging” only a truly *de minimis* number of H. D. Smith’s sales into Cuyahoga County—which includes sales to Church Square Pharmacy—without any evidence from which a jury could infer that such sales ended up in orders that were diverted.

Prescription Supply. “What created and fueled the epidemic . . . is the intentional conduct of Fortune 500 companies.”⁴¹ That was Summit County’s response to Defendants’ motions to dismiss. Plaintiffs’ position today is very different. Prescription Supply, “a family-run business” according to Plaintiffs,⁴² is now somehow a substantial factor in causing the epidemic.

But Plaintiffs’ data analyst, Dr. McCann, disagrees. He testified unequivocally that market share of [REDACTED] percent is *de minimis*⁴³—and in Summit County, Prescription Supply’s market share is [REDACTED] percent.⁴⁴ That is the lowest-registering percentage on McCann’s charts. At least fifteen distributors with the same or greater market share in Summit County have not even been sued.⁴⁵ And for flagged orders in Summit County, Prescription Supply’s shares under Plaintiffs’ five methods are even less: [REDACTED] percent, [REDACTED] percent, [REDACTED] percent, [REDACTED] percent, and [REDACTED] percent.⁴⁶ These figures are the numerical embodiment of *de minimis*.

⁴⁰ *Id.* at 13.

⁴¹ ECF No. 654 at 23.

⁴² ECF Nos. 2200/2201 at 1.

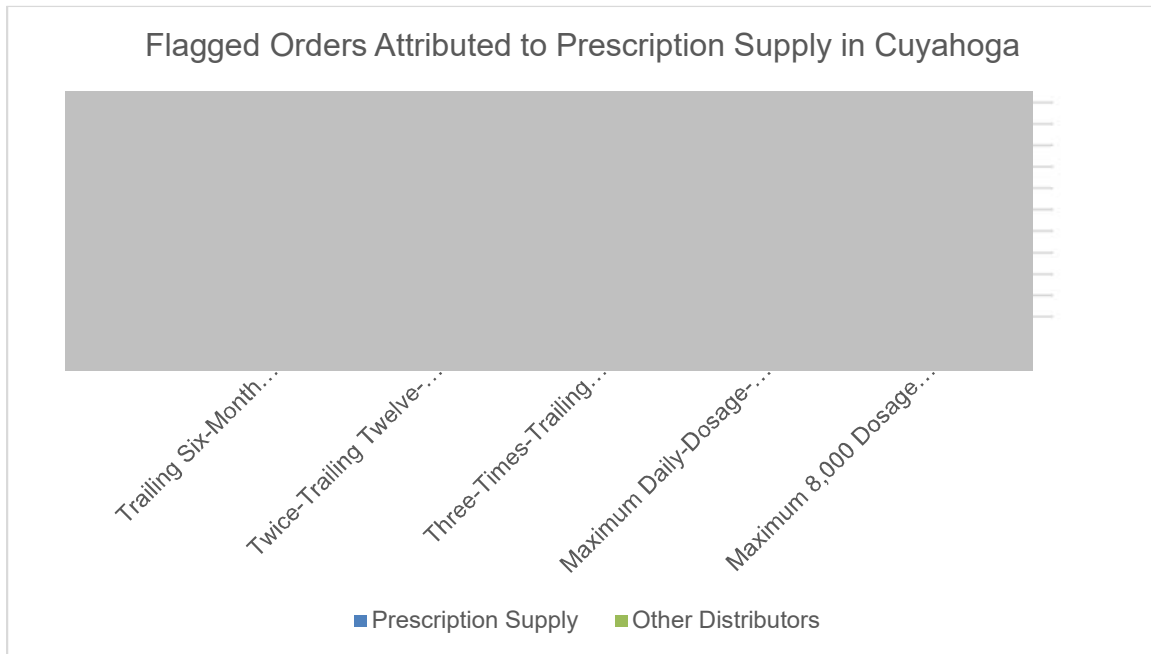
⁴³ ECF No. 1966-17 at 555:11–17.

⁴⁴ ECF No. 2302-1/2306-1 at 3849, 3852.

⁴⁵ *See id.*

⁴⁶ ECF Nos. 1999-13/2000-14 at 60, 64, 68, 72, and 76.

Prescription Supply had similarly little to do—[REDACTED] percent and [REDACTED] percent market share by dosage and MME respectively⁴⁷—in Cuyahoga County. The company’s small number of shipments translates to trivial numbers of flagged orders under all five of Plaintiffs’ methods:⁴⁸



Hamstrung by the math, Plaintiffs take issue with Prescription Supply’s SOMS. While this argument is immaterial to Prescription Supply’s *de minimis* status, the company incorporates its opposition to Plaintiffs’ motion for summary judgment on violations of the CSA asserting almost verbatim the same arguments Plaintiffs do here.⁴⁹

CONCLUSION

For the foregoing reasons, the Court should grant the motion for summary judgment.

⁴⁷ ECF Nos. 2302-1/2306-1 at 3779, 3783.

⁴⁸ See ECF Nos. 1999-13/2000-14 at 59, 63, 67, 71, 75 ([REDACTED]%, [REDACTED]%, [REDACTED]%, [REDACTED]%, and [REDACTED]%, respectively).

⁴⁹ ECF No. 2149 at 53–56.

Dated: August 16, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, John J. Haggerty, certify that the foregoing document was served via the Court's ECF system to all counsel of record.

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